syringe body (1), a piston rod (6) with a piston stopper (5) slidably mounted in said plastic syringe body (1) and a removable cap (4) engageable on said plastic hollow spike (9) to close said syringe body (1);

wherein said plastic hollow spike (9) includes means for piercing the elastomeric closure (11) of the medical container (10), said plastic hollow spike (9) is conical and tapered and said plastic hollow spike (9) has a slant (9a) extending over an entire diameter of said plastic hollow spike at a piercing end of said spike (9) so as to produce an eccentric tip having an edge facilitating penetration of said elastomeric closure;

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whereby an amount of elastomeric particles from said elastomeric closure contaminating said medicinal substances and a danger of injury from the plastic hollow spike are reduced.

REMARKS

This is a preliminary amendment for a continued prosecution application. It is filed in response to the final Office Action in the parent application and to the interview with the Examiner held on August 9, 2001.

In the final Office Action in the parent Application claims 18 to 20 were rejected under 35 U.S.C. 103 (a) over Goodsir, et al, in view of Heinke and/or Gabriel.

Independent claims 18 and 20 have now been amended to further

distinguish them from the cited prior art. The changes in independent claims 18 and 20 were discussed in the interview with the Examiner (see the interview summary of 8/14/01).

The Examiner indicated during the interview that the independent claims should be amended to include a "whereby" clause further distinguishing the "means for piercing". The "whereby" clause has been added and is the following: "whereby an amount of elastomeric particles from said elastomeric closure contaminating said medicinal substances and a danger of injury from the plastic hollow spike are reduced". Basis for this clause is found on page 5, lines 13 to 15, of the originally filed specification.

In addition, additional details regarding the features of the hollow spike were requested. The following phase was added by amendment to the last few lines of each of claims 18 and 19 "so as to produce an eccentric tip having an edge facilitating penetration of said elastomeric closure". This wording is based on the disclosure in applicants' specification at page 5, lines 13 to 15; page 8, lines 1 to 3; and page 11, lines 20 to 23 (the term "sharp-edged" was avoided).

Both claims 18 and 20 contain the following combination of features distinguishing the claimed invention from the disclosures in the various prior art references:

(1) the hollow spike in one piece with the syringe body, both of which are *plastic* to reduce the possibility of injury;

(2) the *conical and tapered* hollow spike;

(3) a *bevel or slant* on the piercing end of the hollow spike produces an

eccentric tip with a comparatively sharp edge that comparatively easily penetrates an elastomeric closure, even though it is of plastic and much less likely to penetrate the skin or a patient or user of the device; and

(4) features (1) to (3) above *dimensioned and designed*

so that an amount of elastomeric particles from said elastomeric closure contaminating said medicinal substances and a danger of injury from the plastic hollow spike are reduced (whereby clause of claims 18 and 20).

Also recitation of these features individually does not mean that applicants are arguing that the individual features are non-obvious, or that a syringe containing just one of these features is non-obvious. Applicants are only arguing the combination of features above, in other words, that claims 18 and 20, the invention as a whole, is not obvious from the art of record.

It is respectfully submitted that the invention claimed in claims 18 and 20, "as a whole" is not suggested by the cited references, e.g. Goodsir, et al; Heinke and/or Gabriel.

First, there is no motivation for one skilled in the art to combine the cited references with each other because they disclose syringes for entirely different purposes. Goodsir, et al, discloses a syringe device for transferring a medicinal substance into a bottle or flexible bag for intravenous delivery of the medicinal substance to a patient *through a valve device* that is activated by insertion of a tubular male tapered section of a hub connector 16 of the syringe device. The tubular male tapered section of hub connector 16, and the hollow needle 14 surrounded by it, are blunt because they only function to displace or move a

movable valve part that opens the valve. However Gabriel discloses a hypodermic syringe device having a detachable hypodermic needle and a detachable stub needle by which the body of the hypodermic syringe may be filled. The detachable stub needle penetrates an elastomeric closure on a bottle containing the medicinal substance in order to fill the body of the hypodermic syringe and thus needs to be comparatively sharp, entirely different from the device of Goodsir, et al. Heinke discloses a one-piece plastic syringe barrel 12 and needle 18. The syringe of Heinke also includes a tip-cap seal, which is elastomeric and used as a guard for the sharp needle 18, thus preventing contamination of the medicinal substance after drawing it from a bottle with an elastomeric closure and providing a convenient shield for spraying the contents into a nostril of an animal without sticking the animal with the needle.

Thus, the references disclose syringes of entirely different types: Heinke describes a syringe for spraying vaccine into the nose of an animal without sticking the animal, Gabriel describes a hypodermic syringe for injecting a medicinal substance subcutaneously and Goodsir, et al, describes a syringe with blunt tip for transferring between a storage bottle and infusion bag through a valve. How could the disclosures of these references be combinable under 35 U.S.C. 103 (a) when the devices serve such different purposes? One skilled in the art would not be motivated to combine these references.

The final Office Action in the parent application does agree that Goodsir, et al, does not disclose a spike that is conical and tapered and provided with a slant or bevel. The Office Action also notes that tapered and conical spikes are

known in the art and also cites references Gabriel and Heinke presumably for the purpose of showing these alternative spikes. However the Office does not explain why one skilled in the art would be motivated to combine the features of the "spike" of Gabriel and/or Heinke with the hollow needle of Goodsir, et al. In order for a claimed invention to be obvious, there must be motivation in the art to combine the disclosures of the prior art references used to reject the claimed invention as obvious. For example, the Board of Patent Appeals and Interferences has said:

> "When the incentive to combine the teachings of the references is not readily apparent, it is the duty of the Examiner to explain why combination of the reference teachings is proper... absent such reasons or incentives, the teachings of the references are not combinable. ***Ex parte Skinner***, 2 U.S.P.Q. 2nd 1788 (B.P.A.I. 1987)

For example, Heinke does disclose a plastic needle tip that is designed to penetrate an elastomeric closure, but Heinke does not provide a slant or a bevel on the end of the tip to facilitate penetration. Gabriel, on the other hand, discloses a needle tip with a bevel or slant in order to penetrate an elastomeric closure. How would one skilled in the art know which alternative to select for the applicants' syringe? There is no suggestion in these two prior art references that one alternative should be selected over the other; i.e. no suggestion of the particular combination of features of claims 18 and 20. No reason or incentive is provided in the art for selecting one alternative tip structure over the other.

In addition the primary reference, Goodsir, et al, teaches away from the claimed invention because Goodsir, et al, requires that the hollow needle 14 and

the male end of the hub connector 16 must be blunt to open the valve disk 50 in the intravenous injection port (column 4, lines 9 to 23). The valve disk 50 would clearly be damaged and the syringe would not function properly if it was penetrated by the tip of the needle 14. In contrast, the claimed invention requires "bevel or slant on the piercing end of the hollow spike produces an eccentric tip with a comparatively sharp edge that comparatively easily penetrates an elastomeric closure". In other words, the claimed invention requires the opposite a sharp tip for the spike for easy penetration of an elastomeric closure. Furthermore, the secondary references also require sharp needle tips, especially the Gabriel reference.

It is well established that references that teach the opposite from each other cannot be combined under 35 U.S.C. 103 (a) to reject a claimed invention. See M.P.E.P. 2145. X. D. 2. For example, the Federal Circuit Court of Appeals has said:

> "That the inventor achieved the claimed invention by doing what those skilled in the art suggested should not be done is a fact strongly probative of nonobviousness." in ***Kloster Speedsteel AB v. Crucible Inc.,*** 230 U.S.P.Q. 81 (Fed. Cir. 1986), on rehearing, 231 U.S.P.Q. 160 (Fed. Cir. 1986).

In this case the teaching regarding the tip of the syringe device of the primary reference, Goodsir, et al, is the *opposite* from the claimed invention, as claimed in claims 18 and 20, as well as from that of the secondary references that are to be combined with it.

In addition, if the disclosure of Goodsir, et al, were to be modified by replacing the blunt tip with the sharp or beveled tip, Goodsir, et al, would be

modified so that it could not perform its intended function, which is improper under 35 U.S.C. 103 (a). M.P.E.P. 2143.01.

Furthermore the invention provides the basis for excluding or reducing contamination by elastomeric particles, which can be trapped in a needle tip when it is inserted in an elastomeric closure. The use of the plastic tip which is conical and tapered and has a slant or bevel provides the basic structure which can be dimensioned and controlled so that the presence of elastomeric particles in the transferred contents of the syringe are minimized. This feature is included in claims 18 and 20 by the "whereby" clauses at the end of these claims.

The problem of reducing contamination of transferred syringe contents with elastomeric particles is not disclosed in any of the three cited references and its solution as claimed in claims 18 and 20 is not suggested by the references taken singly or in combination with each other.

It is respectfully submitted that one skilled in the art would only arrive at the invention claimed in claims 18 and 20 (minus the features reducing elastomer particle contamination) from the prior art of record by an impermissible use of hindsight using the applicants' specification as a guide to pick and choose elements of the prior art devices to reconstruct the claimed invention. This kind of hindsight reconstruction is not permitted under 35 U.S.C. 103 (a). For example, the Federal Circuit Court of Appeals has said:

> "As in all determinations under 35 U.S.C. 103, the decision maker must bring judgment to bear. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selected elements from references to fill the

gaps". ***In re Gorman***, 18 U.S.P.Q.2d 1885 (Fed. Cir. 1991).

For the foregoing reasons it is respectfully submitted that the rejection of claims 18 to 20 under 35 U.S.C. 103 (a) over Goodsir, et al, in view of Heinke and/or Gabriel should be withdrawn.

APPENDIX SHOWING CHANGES REQUIRED TO OBTAIN THE REPLACEMENT CLAIMS 18 AND 20

18(AMENDED). A syringe for transferring a medical substance from a medical container provided with an elastomeric closure into an infusion container, said syringe comprising a plastic syringe body (1) having a front end and including a plastic hollow spike (9), wherein said plastic hollow spike (9) is arranged at said front end of said plastic syringe body (1) and is in one-piece with said plastic syringe body (1), said plastic hollow spike (9) includes means for piercing the elastomeric closure (11) of the medical container (10), said plastic hollow spike (9) is conical and tapered and said plastic hollow spike (9) is provided with a bevel (9a) extending over an entire diameter of said plastic hollow spike at a piercing end of said hollow plastic spike (9) so as to produce an eccentric tip having an edge facilitating penetration of said elastomeric closure;

whereby an amount of elastomeric particles from said elastomeric closure contaminating said medicinal substances and a danger of injury from the plastic hollow spike are reduced.

20(AMENDED). A syringe for transferring a medical substance from a medical container provided with an elastomeric closure into an infusion container, said syringe consisting of a plastic syringe body (1) having a front end and including a plastic hollow spike at said front end which is in one piece with said plastic syringe body (1), a piston rod (6) with a piston stopper (5) slidably mounted in said plastic syringe body (1) and a removable cap (4) engageable on said plastic hollow spike (9) to close said syringe body (1);

wherein said plastic hollow spike (9) includes means for piercing the elastomeric closure (11) of the medical container (10), said plastic hollow spike (9) is conical and tapered and said plastic hollow spike (9) [is provided with a bevel (9a)] has a slant (9a) extending over an entire diameter of said plastic hollow spike at a piercing end of said spike (9) so as to produce an eccentric tip having an edge facilitating penetration of said elastomeric closure;

whereby an amount of elastomeric particles from said elastomeric closure contaminating said medicinal substances and a danger of injury from the plastic hollow spike are reduced.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Any costs involved should be charged to the deposit

account of the undersigned (No. 19-4675). Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

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